United States District Court

Northern District of Ohio

Eastern Division

In Re National Prescription	MDL 2804
Opiate Litigation	Case No. 17-md-2804
This document relates to:	Hon. Dan Aaron Polster
Track One Cases	

PARTIES' JOINT STIPULATION

The parties to the above-entitled action, having met and conferred[1], and upon determining that good cause exists for the foregoing, hereby stipulate as follows:

1. 21 U.S.C. § 801 et seq., the Controlled Substances Act ("CSA"), is a federal statute that applies to each substance regulated under federal law.

2. Congress enacted the CSA in 1970.

3. The Drug Enforcement Agency ("DEA") is the federal agency responsible for the implementation and enforcement of regulations corresponding to the CSA.

4. DEA regulates the closed system for drug distribution in the United States.

5. DEA promulgated regulations, 21 C.F.R. § 1301.01 et seq., to implement the CSA in 1971.

6. "Suspicious orders," pursuant to 21 C.F.R. § 1301.74(b), "include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency."

[1] The parties continue to meet and confer on several additional proposed facts.

7. As part of the closed system for drug distribution, every manufacturer, distributor, pharmacy, pharmacist, and prescriber in the supply chain that handle controlled substances must be registered with DEA.

8. The CSA establishes five schedules of controlled substances: Schedule I, Schedule II, Schedule III, Schedule IV, and Schedule V controlled substances.

9. Oxycodone is classified as a Schedule II controlled substance.

10. DEA was a member of the Suspicious Order Task Force pursuant to the Comprehensive Methamphetamine Control Act of 1996.

11. DEA's Internet Distributor Initiative commenced in July 2005.

12. Manufacturers and Distributors are required to report all transactions involving Schedule II controlled substances and transactions involving certain Schedule III narcotics to DEA's Automation of Reports and Consolidated Order System ("ARCOS").

13. ARCOS also contains records of manufacturers' transactions involving other selected Schedule III and IV psychotropic drugs.

14. DEA can and does use ARCOS data to create summary reports showing how many controlled substances were manufactured and distributed throughout the United States.

15. Data from ARCOS has been available to DEA and other federal law-enforcement officials since 1996.

16. The documents produced by the United States Drug Enforcement Administration ("DEA") related to the Automated Records and Consolidated Orders System ("ARCOS Data") reflecting transactions in drug products containing one or more of fourteen drugs: buprenorphine, codeine, dihydrocodeine, fentanyl, hydrocodone, hydromorphone, levorphanol, meperidine, methadone, morphine, powdered opium, oxycodone, oxymorphone, and tapentadol for the period of January 1, 2006 through December 31, 2014 shall be deemed authentic and presumed admissible for the purposes of this litigation.

17. Cardinal Health, Inc. is an Ohio corporation and is headquartered in Dublin, OH.

18. From at least 1995 to 2007, each of Cardinal Health's more than two dozen distribution centers submitted an ILR each month to the DEA.

19. Walgreen Co. is an Illinois corporation with its principal place of business in Deerfield, Illinois.

20. Walgreen Eastern Co., Inc. is a New York corporation with its principal place of business in Deerfield, IL.

21. Walgreens operates a national retail pharmacy chain.

22. AmerisourceBergen Drug Corporation is incorporated in Delaware and its principal place of business is located in Chesterbrook, PA.

23. Anesta Corporation initially sought approval from the United States Food and Drug Administration ("FDA") for Actiq.

24. Cephalon acquired the rights to Actiq in October 2000.

25. Fentora was approved by the FDA on September 25, 2006 for the management of breakthrough pain in patients with cancer who are already receiving and who are tolerant to opioid therapy for their underlying persistent cancer pain.

26. Actiq and Fentora are both "branded" medicines because they were sold pursuant to an FDA-approved New Drug Application ("NDA), under a brand name (Actiq or Fentora).

27. Teva Ltd. is the indirect parent company of Teva USA, Cephalon, Watson Labs, Actavis LLC, Actavis Pharma, Warner Chilcott, Actavis South Atlantic, Actavis Elizabeth, Actavis Mid Atlantic, Actavis Totowa, Actavis Kadian, Actavis Labs UT, and Actavis Labs FL.

28. Teva Ltd. became the indirect parent of Cephalon in October 2011.

29. Teva USA is a Delaware corporation with its principal place of business in North Wales, Pennsylvania.

30. Prior to October 2011, Teva USA did not manufacture or sell any branded opioid medicines.

31. Cephalon is a Delaware corporation with its principal place of business in West Chester, Pennsylvania.

32. FDA approved each of the opioid medicines sold by Teva USA, Cephalon, Watson Labs, Actavis LLC, Actavis Pharma, Warner Chilcott, Actavis South Atlantic, Actavis Elizabeth, Actavis Mid Atlantic, Actavis Totowa, Actavis Kadian, Actavis Labs UT, and Actavis Labs FL before they were sold or marketed in the United States.

33. Johnson & Johnson is a New Jersey Corporation with principal place of business in New Brunswick, NJ.

34. Janssen Pharmaceuticals, Inc. ("Janssen") is a Pennsylvania corporation with its principal place of business in Titusville, NJ and is a wholly-owned subsidiary of Johnson &Johnson.

35. Janssen Pharmaceuticals, Inc. formerly was known as Ortho-McNeil-Janssen Pharmaceuticals, Inc., which in turn was fka Janssen Pharmaceutica, Inc.

36. Ortho-McNeil-Janssen Pharmaceuticals, Inc., nka Janssen Pharmaceuticals, Inc., was a Pennsylvania corporation with its principal place of business in Titusville, NJ.

37. Janssen Pharmaceutica, Inc., nka Janssen Pharmaceuticals, Inc., was a Pennsylvania corporation with its principal place of business in Titusville, NJ.

38. Janssen sold the opioid products (1) Duragesic, (2) Nucynta IR, and (3) Nucynta ER for certain periods of time.

39. The FDA approved Duragesic 25-100 ug/hr fentanyl patches on August 7, 1990.

40. The FDA approved Duragesic 12.5 ug/hr fentanyl patches on February 4, 2005.

41. Janssen previously manufactured Nucynta IR (immediate-release tapentadol hydrochloride) in 50, 75, and 100 mg doses.

42. The FDA approved Nucynta IR 50-100 mg on November 20, 2008.

43. Nucynta IR entered the market in June 2009.

44. Janssen no longer sells Nucynta IR or ER, having divested those products in 2015 to Depomed, Inc., an American specialty pharmaceutical company.

45. Janssen previously manufactured Nucynta ER (extended-release tapentadol hydrochloride) in 50, 100, 150, 200, and 250 mg doses.

46. The FDA approved Nucynta ER 50-250 mg on August 25, 2011.

47. Nucynta ER entered the market in September 2011.

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Respectfully Submitted,

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